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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/508,054 | 04/20/2000 | FRANK MAN-WOON NG | 017227/0156 | 4140 |

7590 07/29/2002

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| EXAMINER | |
|---|---|
| SAOUD, CHRISTINE J | |
| ART UNIT | PAPER NUMBER |
| 1647 | |

DATE MAILED: 07/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/508,054 | Applicant(s) NG et al. |
|---|---|---|
| | Examiner Christine Saoud | Art Unit 1647 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *May 9, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1, 7-18, 34, and 36-40* is/are pending in the application.

4a) Of the above, claim(s) *8-10, 12, 14, 15, 17, 18, 34, 38, and 40* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 7, 11, 13, 16, 36, 37, and 39* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Response to Amendment*

1. Claims 1, 13-17, 34, 36 have been amended and claims 39-40 (renumbered from the original 37-38; see rule 1.121) have been added as requested in the amendment of paper #14, filed 09 May 2002. Claims 1, 7-18, 34, 36-40 are pending in the instant application.

### *Election/Restriction*

2. Applicant's election without traverse of Group I in Paper No. 12 is acknowledged.

3. Claims 17-18, 34, 38 and 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 12.

Applicant's election of the peptide of SEQ ID NO:19 is noted in paper #14. It would appear that claims 8-10, 12, 14, 15 do not encompass the elected peptide. Therefore, these claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made without traverse in Paper #14. Claims 1, 7, 11, 13, 16, 36-37 and 39 are under examination.

### *Priority*

4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 371 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

***Double Patenting***

5. Claim 39 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 37. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 7, 11, 36, 37, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Wade et al. (Acta Endocrinologica 101: 10-14, 1982).

Wade et al. disclose a peptide of human growth hormone consisting of amino acids 177-191 of the human growth hormone. Wade et al. teach that the protein has a disulfide bond

between the cysteine residues found at positions 182 and 189. Wade et al. further administered the peptide to rats to test the hyperglycaemic action of the peptide, thereby disclosing pharmaceutical compositions thereof (see page 11, column 1, paragraph 3). Wade et al. do not disclose an amide covalent bond between residues 183 and 186. However, in view of the disulfide bond which is normally formed, these amino acids would be in close proximity to one another and owing to their positive and negative charges, the amide bond would be inherent to the peptide of Wade et al. absent evidence to the contrary. Therefore, the claims are anticipated by Wade et al.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 7, 11, 13, 16, 36, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wade et al. in view of Ma et al. (Biochim. Biophys. Acta 716: 400-409, 1982) and Nicoll et al. (Endo. Rev. 7(2): 169-203, 1986).

The disclosure of Wade et al. is as described above. Wade et al. do not teach a peptide of human growth hormone 176-191 which has a Tyrosine at position 176 (the elected species). Ma et al. teach that a peptide of human growth hormone consisting of amino acids 176-191 of human growth hormone has similar hyperglycaemic activity to the 177-191 peptide of Wade et al. Nicoll

et al. disclose the amino acid sequences of 9 species of growth hormone. Figure 1 at page 173 of Nicoll et al. teaches amino acids which are identical as well as those amino acids which would be considered "highly acceptable substitutions", which includes position 176 (tyrosine in all the species listed except for the human). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to generate a peptide of human growth hormone corresponding to amino acids 176-191 of human growth hormone with a substitution of tyrosine at position 176 because (1) Wade et al. teach that the 177-191 peptide is useful for it's hyperglycaemic activity, (2) Ma et al. teach that the extended peptide of 176-191 is equally useful and (3) Nicoll et al. teach that many amino acids may be substituted in growth hormone, including position 176 to tyrosine, which is the naturally occurring amino acid in all species exemplified except for humans. One would be motivated to make the substitution and have a reasonable expectation of success in substituting the amino acid tyrosine for the native amino acid in the 176-191 peptide of Ma et al. because Nicoll et al. teaches that it is an acceptable substitution and because it is the naturally occurring amino acid in most other species of growth hormone. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time it was made absent evidence to the contrary.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 3PM. If attempts to

reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud